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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/731,899

12/08/2000

Benjamin Chain

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1183

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7590

02/25/2009

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EXAMINER

SWARTZ, RODNEY P

ART UNIT

PAPER NUMBER

1645

MAIL DATE

DELIVERY MODE

02/25/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 09/731,899	<b>Applicant(s)</b> CHAIN, BENJAMIN	
	<b>Examiner</b> Rodney P. Swartz, Ph.D.	<b>Art Unit</b> 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 20 January 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-5,7-15,21-25 and 27-35 is/are pending in the application.
- 4a) Of the above claim(s) 13-15 and 33-35 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 21-25,27-32 is/are allowed.
- 6) ☒ Claim(s) 1,7,10 and 11 is/are rejected.
- 7) ☒ Claim(s) 2-5,8,9 and 12 is/are objected to.
- 8) ☒ Claim(s) 1-5,7-15,21-25 and 27-35 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. **THE FINALITY OF THE LAST OFFICE ACTION IS HEREBY VACATED.**
2. Applicant's Response to Office Action, received 20 January 2009, is acknowledged.  
Claims 1, 7, 21, 27 and 28 have been amended. Claims 6 and 26 have been canceled.
3. Claims 1-5, 7-15, 21-25 and 27-35 are pending. Claims 13-15 and 33-35 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention.
4. Claims 1-5, 7-12, 21-25 and 27-32 are under consideration.

### **Rejections Withdrawn or Moot**

5. The rejection of claims 1-5, 10, and 21-25 under 35 U.S.C. 102(e) as being anticipated by Perl (U.S. Pat. No. 5,879,909), is withdrawn in light of the amendments of the claims.
6. The objection to claims 7-12 and 27-32, being dependent from rejected claims, is withdrawn.
7. The objection to claims 6 and 26, being dependent from rejected claims, is moot in light of the cancellation of the claims.

### **Claim Rejections - 35 USC § 102**

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1, 7, 10 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Frazer et al (WO98/23635, 4 June 1998).

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Newly amended claim 1 is drawn to a chimeric peptide of formula (I) or (II) or mixtures of (I), or (II), or (I) and (II). N is designated as being 2, 3, 4, or 5 amino acids, C is designated as being 2, 3, 4, or 5 amino acids. S is a spacer amino acid residue, T<sub>h</sub> is a promiscuous T helper cell epitope, m is 0-5 and n is 1-4.

The recitation in the claims that N originates from the free N-terminus of a naturally occurring internal peptide cleavage product formed by proteolytic cleavage of a precursor protein or mature protein, or that C is the last 2-5 amino acid residues from the free C-terminus of a naturally occurring internal peptide cleavage product that is formed by proteolytic cleavage of a precursor protein or a mature protein is merely a product by process, and does not place any patentable structure characteristic on the final product, i.e., the claimed chimeric peptide, which would differentiate the claimed peptides from peptides made by another process.

Frazer et al teach a chimeric peptide of formula (I), i.e., 2-4 amino acids attached to a promiscuous T helper cell epitope (Abstract; page 9, lines 5-16; page 9, line 28 to page 10, line 3). Frazer et al teach that the promiscuous T helper cell epitope may be from a variety of sources, e.g., tetanus toxin, *Plasmodium falciparum* circumsporozoite protein, measles virus F protein (page 4, lines 15-30). Frazer et al teach composition to generate an immune response (Abstract; page 33, line 1 to page 40, line 14).

### **Claim Objections**

10. Claims 2-5, 8, 9 and 12 are objected to because they depend from rejected claims.

### **Conclusion**

11. Claims 1-5 and 7-12 are not allowed. Claims 21-25 and 27-32 appear to be free of the prior art.

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12. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Wednesday from 9:00 AM to 7:30 PM EST. Thursday is the examiner's work at home day.

If attempts to reach the Examiner by telephone are unsuccessful, please contact the Examiner's Supervisor, Robert B. Mondesi (571)272-0956.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Rodney P. Swartz, Ph.D./

Primary Examiner, Art Unit 1645

February 25, 2009